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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/510,655

11/30/2004

Hans Groenlund

LNK-031

9022

31496 7590 12/28/2010
SMITH PATENT CONSULTING, LLC
515 East Braddock Road
Suite B
ALEXANDRIA, VA 22314

EXAMINER

ROONEY, NORA MAUREEN

ART UNIT

PAPER NUMBER

1644

NOTIFICATION DATE

DELIVERY MODE

12/28/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

chalin@smithpatent.com

Office Action Summary	Application No. 10/510,655	Applicant(s) GROENLUND ET AL.	
	Examiner NORA M. ROONEY	Art Unit 1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 March 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 25-35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 25-29 and 32-35 is/are rejected.
- 7) ☒ Claim(s) 30 and 31 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>03/01/2010</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 03/01/2010 has been entered.
2. Claims 25-35 are pending and under consideration as they read on a microparticle comprising a bead and a plant pollen allergen.
3. Applicant's IDS document filed on 03/01/2010 is acknowledged.
4. Applicant's response, Exhibits A-C and the Declaration of Rudolf Valenta filed on 03/01/2010 are sufficient to overcome the rejections under 112, first paragraph that were presented in the Office Action mailed on 05/29/2009.
5. It is noted from the response that the Examiner has been clear on the definition of the term CBP as meaning carbohydrate based particle. Cyanogen bromide activated spherical Sepharose particles are carbohydrate based particles and the specification uses the exact terminology used by the Examiner on page 7, line 11. It is additionally noted that the CBPs that were taught in Gronland and Neimart-Andersson, which Applicant claims that the Examiner has

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mischaracterized, are cyanogen bromide activated spherical Sepharose particles. So, even though the term CBP is generic, all of the CBPs in the references and specification are cyanogen bromide activated spherical Sepharose particles.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 29 and 32-33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 29 and 33 recite "the Phl p 5b allergen of SEQ ID NO:1." However, there are no sequences disclosed in this application. The recitation of SEQ ID NO:1 makes these claims indefinite.

Claim 32 recites a mean diameter "on the order of 2 μ m." "On the order of" is a relative term which renders the claim indefinite. The term "on the order of" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Correction is required.

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 29 and 33 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for the same reasons as set forth in the Office Action mailed on 04/01/2008. This is a New Matter rejection.

The phrase "the Phl p 5b allergen of SEQ ID NO:1" in claims 29 and 33 represents a departure from the specification and the claims as originally filed.

Applicant does not point to the specification for support for the newly added limitation "the Phl p 5b allergen of SEQ ID NO:1" in claims 29 and 33 and it appears that the specification does not provide clear support for the term. The instant claims now recite limitations which were not clearly disclosed in the specification and recited in the claims as originally filed.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claims 25-28 and 34-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sobotka et al. (PTO-892; Reference U) in view of Van Ree et al. (PTO-892; Reference V).

Sobotka et al. teaches a composition comprising cyanogen bromide activated Sepharose 4B (a three dimensionally cross-linked agarose bead, activated spherical agarose) coupled by a

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covalent bond to purified recombinant phospholipase A (honeybee allergen) suspended in RAST buffer (formulated as an injectable solution, parenteral solution) used to diagnose allergic patients (In particular, page 2478, paragraph spanning left and right columns). The reference teaches that "sera can be analyzed by RAST with little inconvenience or danger to the patient. Since accurate diagnosis in this potentially life threatening disease is of primary importance, development and assessment of the potential of the RAST in this disease state seemed necessary." (In particular, page 2477, right column, second full paragraph).

It is noted that the instant claims are drawn to a product, not to a method. Therefore, the intended use of "medicament," "for allergen-specific immunotherapy" and "wherein said medicament is capable of inducing a strong allergen-specific IgG response comparable to that of an equivalent Alum-bound allergen with less granulomatous tissue reactions as compared to said Alum-bound allergen" in claim 25 do not carry patentable weight per se. The claims read on the active or essential ingredients of the composition and the microparticles in RAST buffer are not incompatible with pharmaceutical and/or medicinal use.

The claimed invention differs from the prior art in the recitation of "a purified recombinant polypeptide allergen derived from plant pollen" in claim 25; "wherein the allergen is a grass pollen allergen" in claim 27, "wherein the allergen is a timothy grass pollen allergen" of claim 28.

Van Ree et al. teaches that Group 1 and Group 5 allergens are the two most important allergens in grass pollen (In particular, page 184). The reference teaches using recombinant Phl p1 and Phl p 5 coupled by a covalent bond to Sepharose in a RAST for IgE reactivity to diagnose patients allergic to the most important timothy grass pollen major allergens (In particular, abstract, page 184, whole document).

It would have been obvious to one of ordinary skill in the art at the time of invention to couple recombinant Phl p1 and Phl p 5 to the cyanogen bromide activated Sepharose 4B beads of Sobotka et al. since Sobotka et al teaches that using their method sera can be analyzed by RAST with little inconvenience or danger to the patient. It would have been obvious to perform the RAST of Van Ree et al. using Phl p1 and Phl p 5 covalently couple to the cyanogen bromide activated Sepharose 4B beads suspended in RAST buffer in order to diagnose timothy pollen allergic patients having reactivity to the two most important major allergens Phl p 1 and Phl p 5.

It is noted that the combination of the reference results in the claimed medicament, though the reason for combining the references to arrive at the claimed compositions is not the same as disclosed in the instant application, namely for in vivo use. The resulting composition is not incompatible with medicinal and/or pharmaceutical use. In addition, as confirmed by Applicant's response on page 6 of the response filed on 03/01/2010 that data confirms "the utility of particles of varying size, in addition to varying substrate material and allergen type." Therefore, Applicant acknowledges on the record that the compositions of the type that results from the combination of the above two references would work for its intended purpose.

From the reference teachings, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the reference, especially in the absence of evidence to the contrary.

12. No claim is allowed.

13. Claims 30 and 31 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. It is noted that this is based upon the Examiner's research on sepharose beads all being larger than .1 to 10 μm .

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nora M. Rooney whose telephone number is (571) 272-9937. The examiner can normally be reached Monday through Friday from 8:30 am to 5:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

December 18, 2010

/Nora M Rooney/

Primary Examiner, Art Unit 1644